K093560

SECTION 5 – 510(k) SUMMARY

JAN 28 2010

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www.upcera-dental.com

Date Prepared

August 14, 2009

Trade Name

Upcera Zirconia Blanks

Regulation Name

Porcelain Powder for Clinical Use

Regulation Number

872.6660

Classification Name

Powder, Porcelain

Product Code(s)

EIH

Classification Panel

Dental Devices

Regulatory Class

Class II

Device Description

Upcera Zirconia Blanks are derived from zirconia powder that has been processed into their final net shapes. These blanks are then further fabricated into various prosthetic dental devices intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Intended Use

Upcera Zirconia Blanks are intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Predicate Device

K081850 - Bisque Zirconia Blanks, Type BYZ

Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the **Upcera Zirconia Blanks** and the predicate device do not raise any questions regarding its safety and effectiveness. **Upcera Zirconia Blanks**, as designed and manufactured, are as safe and effective as the predicate device and therefore is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shenyang Upcera Company, Limited
C/O Mr. Stuart R. Goldman
Senior Consultant
Emergo Group, Incorporated
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JAN 28 2010

Re: K093560
Trade/Device Name: Upcera Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 10, 2009
Received: November 21, 2009

Dear Mr Goldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093560

Device Name:

Upcera Zirconia Blanks

Indications for Use:

Upcera Zirconia Blanks are intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093560